CLAIMS

We claim:

1) A pharmaceutical composition comprising:
   a) oxybutynin;
   b) a second drug for treating incontinence, wherein the second drug is selected from the group consisting of darifenacin, duloxetine and tolterodine; and
   c) at least one pharmaceutical excipient.
2) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is present as a manufactured batch.
3) The pharmaceutical composition of claim 2 comprising:
   a) a homogeneous mixture of oxybutynin, the second drug and at least one pharmaceutical excipient.
4) The pharmaceutical composition of claim 2 comprising:
   a) a heterogeneous mixture of oxybutynin, the second drug and at least one pharmaceutical excipient.
5) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is present as a unit dose.
6) The pharmaceutical composition of claim 5, wherein at least one of the oxybutynin and the second drug is present in a therapeutically effective amount.
7) The pharmaceutical composition of claim 5, wherein the oxybutynin and the second drug are each present in a therapeutically effective amount.
8) The pharmaceutical composition of claim 5, wherein at least one of the oxybutynin and the second drug is present in a sub-therapeutically effective amount.
9) The pharmaceutical composition of claim 5, wherein the oxybutynin and the second drug are present in sub-therapeutically effective amounts.
10) The pharmaceutical composition of claim 5 comprising:
   a) a homogeneous mixture of oxybutynin, the second drug and at least one pharmaceutical excipient.
11) The pharmaceutical composition of claim 5 comprising:
   a) a heterogeneous mixture of oxybutynin, the second drug and at least one pharmaceutical excipient.

12) The pharmaceutical composition of claim 1, 2 or 5, wherein the weight ratio of oxybutynin to second drug ranges from 1:0.1 to 1:20.

13) A dosage form comprising:

a) oxybutynin;

b) a second drug for treating incontinence, wherein the second drugs is selected from the group consisting of darifenacin, duloxetine and tolterodine; and

c) at least one pharmaceutical excipient.

14) The dosage form of claim 13 comprising:

a) a first composition comprising oxybutynin and at least one pharmaceutical excipient; and

b) a different second composition comprising the second drug and at least one pharmaceutical excipient.

15) The dosage form of claim 14, wherein the first and second compositions are in admixture.

16) The dosage form of claim 14, wherein the first and second compositions are separate.

17) The dosage form of claim 16, wherein the first and second compositions are in contact with one another.

18) The dosage form of claim 13, wherein at least one of the oxybutynin and the second drug is present in a sub-therapeutically effective amount

19) The dosage form of claim 18, wherein the oxybutynin and second drug together provide a synergistic therapeutic effect when the dosage form is administered to a subject.

20) The dosage form of claim 13, wherein the oxybutynin and second drug are present in therapeutically effective amounts.

21) The dosage form of claim 13, wherein the release profile for oxybutynin and the second drug is independently selected from a controlled, delayed, extended, pulsatile, sustained, immediate, timed, slow, immediate or rapid release when the dosage form is exposed to an aqueous environment.

22) The dosage form of claim 21, wherein oxybutynin and the second drug have approximately the same release profile.

23) The dosage form of claim 21, wherein oxybutynin and the second drug have different release profiles.

24) The dosage form of claim 21, wherein the dosage form provides a controlled release of oxybutynin and the second drug.

25) The dosage form of claim 24, wherein the dosage form provides therapeutically effective plasma levels of oxybutynin and the second drug for a period of at least 12 hours after administration when administered to a subject.

26) The dosage form of claim 13, wherein the dosage form, when administered to a subject, provides an improved toxicity profile as compared to oxybutynin or the second drug when either agent is administered alone to the same subject.

27) The dosage form of claim 13, 18, 20, 21 or 26, wherein the dosage form is selected from the group consisting of a tablet, osmotic device, capsule, tape, suspension, liquid, implant, gel, pill, cream, ointment, inhaler, paste, troche, lozenge, bead, granule, granulation, spheroid, particulate solid, reconstitutable solid, powder, extruded solid, suppository, stick, and mini-pump.

28) A method of treating incontinence in a subject comprising the step of administering a pharmaceutical composition according to any one of claims 1, 5, 6, 8, 10, 11.

29) A method of treating incontinence in a subject comprising the step of administering a dosage form according to any one of claims 13-16, 18, 20-23 or 26.

30) A coated solid dosage form comprising:

a) a core comprising oxybutynin, a second drug for treating incontinence and at least one pharmaceutical excipient, wherein the second drug is selected from the group consisting of darifenacin and tolterodine; and

b) a wall enveloping the core.

31) The dosage form of claim 30, wherein the core comprises:

a) a first composition comprising oxybutynin and at least one pharmaceutical excipient; and

b) a different second composition comprising the second drug and at lease one pharmaceutical excipient.

32) The dosage form of claim 31, wherein the first and second compositions are in admixture.

33) The dosage form of claim 31, wherein the first and second compositions are separate.

34) The dosage form of claim 33, wherein the first and second compositions are in contact with one another.

35) The dosage form of claim 34, wherein the first and second compositions are in stacked arrangement.

36) The dosage form of claim 30 or 31, wherein the release profile for oxybutynin and the second drug is independently selected from a controlled, delayed, extended, pulsatile, sustained, timed, or slow release when the dosage form is exposed to an aqueous environment.

37) The dosage form of claim 36, wherein the dosage form provides a controlled release of oxybutynin and the second drug.

38) The dosage form of claim 36, wherein oxybutynin and the second drug have approximately the same release profile.

39) The dosage form of claim 36, wherein oxybutynin and the second drug have different release profiles.

40) The dosage form of claim 30 or 31, wherein the dosage form is selected from the group consisting of a tablet, bead, osmotic device, granule, suppository, implant, pill, troche, lozenge, and stick.

41) The dosage form of claim 30, wherein the core comprises a homogeneous or heterogeneous mixture of oxybutynin, the second drug and at least one pharmaceutical mixture.

42) The dosage form of claim 41, wherein the wall is microporous, permeable, semipermeable or impermeable.

43) The dosage form of claim 42, wherein the wall further comprises one or more preformed passageways to permit release of oxybutynin and the second drug when the dosage form is exposed to an aqueous environment.

44) The dosage form of claim 41, wherein the wall is a multi-layered wall comprising two or more laminas that are independently selected at each occurrence from inert and drug-containing.

45) The dosage form of claim 44, wherein the two or more laminas are independently selected at each occurrence from microporous, permeable, semipermeable and impermeable.

46) The dosage form of claim 44, wherein the two or more laminas are independently selected at each occurrence from water soluble and water erodible.

47) The dosage form of claim 41, wherein the wall is inert or contains drug.

48) The dosage form of claim 47, wherein the wall is water soluble or water erodible.

64) An osmotic device comprising:

a) a core comprising a first composition comprising oxybutynin and at least one pharmaceutical excipient, and a different second composition comprising a second drug, selected from the group consisting of darifenacin, duloxetine and tolterodine, and at least one pharmaceutical excipient; and

b) a semipermeable membrane enveloping the core and having at least two passageways to permit controlled release of oxybutynin and the second drug from the core when the osmotic device is exposed to an aqueous environment, wherein at least one passageway is in communication with the first composition and at least one passageway is in communication with the second composition.

65) The osmotic device of claim 64, wherein the first and second compositions contact one another and are in stacked arrangement.

66) The osmotic device of claim 64, wherein, when the osmotic device is exposed to an aqueous environment, oxybutynin is released approximately as follows:

Time (hours)	Minimum Amount Released (%)	Maximum Amount Released (%)
1	0	10
3	5	25
7	20	50
11	40	70
15	58	84
19	70	89
24	76	100

67) The osmotic device of claim 66, wherein the osmotic device provides plasma levels for oxybutynin in the range of about 1-12 ng per ml of plasma.

68) The osmotic device of claim 64, wherein, the second drug is darifenacin and is released approximately as follows when the osmotic device is exposed to an aqueous environment:

Time (hours)	Minimum Amount Released (%)	Maximum Amount Released (%)
1	0	12
3	10	35

Time (hours)	Minimum Amount Released (%)	Maximum Amount Released (%)
7	25	65
11	45	89
15	90	98
24	89	100

69) The osmotic device of claim 64 or 65, the second drug is darifenacin and is released approximately as follows when the osmotic device is exposed to an aqueous environment:

Time (hours)	Minimum Amount Released (%)	Maximum Amount Released (%)
1	0	5
3	0	15
7	10	45
11	29	74
15	52	84
19	60	89
24	80	100

70) The osmotic device of claim 64 or 65, wherein the second drug is tolterodine and is released approximately as follows when the osmotic device is exposed to an aqueous environment:

Time (hours)	Minimum Amount Released (%)	Maximum Amount Released (%)
1	0	12
3	3	25
5	17	36
7	31	50
9	49	66
11	61	76
15	74	90
24	76	100

71) The osmotic device of claim 64 or 65, wherein the release of oxybutynin and/or the second drug is delayed.

72) A method of treating incontinence in a subject comprising the step of administering a dosage form according to claim 36.

73) A method of treating incontinence in a subject comprising the step of administering a dosage form according to claim 30-33, 41, 42, 44 or 47.

74) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 64-66 or 68.

106) The dosage form of claim 14, wherein at least one of the oxybutynin and the second drug is present in a sub-therapeutically effective amount

107) The dosage form of claim 14, wherein the oxybutynin and second drug are present in therapeutically effective amounts.

108) The dosage form of claim 13 comprising:

a) a homogeneous or homogeneous mixture of oxybutynin, the second drug and at least one pharmaceutical excipient.

109) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 69.

110) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 70.

111) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 71.

112) An osmotic device comprising:

a) a core comprising a first composition comprising oxybutynin and at least one pharmaceutical excipient, and a different second composition comprising a second drug, selected from the group consisting of darifenacin, duloxetine and tolterodine, and at least one pharmaceutical excipient, wherein the first and second compositions contact one another and are in stacked arrangement; and

b) a semipermeable membrane enveloping the core and having at least two passageways to permit controlled release of oxybutynin and the second drug from the core when the osmotic device is exposed to an aqueous environment, wherein at least one passageway is in communication with the first composition and at least one passageway is in communication with the second composition;

wherein, when the osmotic device is exposed to an aqueous environment, oxybutynin is released approximately as follows:

Time (hs)	Amount Released (%)	
	Min	Max
1	0	10
3	5	25
5	17	36
7	20	50
11	40	70
15	58	85
19	70	90
24	76	100

113) The osmotic device of claim 112, wherein, when the osmotic device is exposed to an aqueous environment, the second drug is released approximately as follows:

Time (hs)	Amount Range (%)	
	Min	Max
1	0	12
3	3	25
5	17	36
7	31	50
9	49	66
11	61	76
15	74	90
24	76	100

114) The osmotic device of claim 112 or 113, wherein the second drug is darifenacin, and the osmotic device provides a single dose plasma level for darifenacin that is sufficient to provide the desired therapeutic response.

115) The osmotic device of claim 112 or 113, wherein the second drug is tolterodine, and the osmotic device provides a single dose plasma level for tolterodine in the range of about 0.5 to 25 ng per ml of plasma.

116) The osmotic device of claim 112 further comprising at least one external coat exterior to the membrane.

117) The osmotic device of claim 116, wherein the external coat is independently selected at each occurrence from water soluble and water erodible.

118) The osmotic device of claim 116, wherein the external coat is independently selected at each occurrence from inert and drug-containing.

119) The osmotic device of claim 116, wherein the external coat is independently selected at each occurrence from microporous, permeable, semipermeable and impermeable.

120) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 112, 113, 116-118 or 119.

121) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 114.

122) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 115.